

Remarks

Applicants respectfully request reconsideration of this application in view of the following remarks.

Status of the Claims

Claims 41-51 are pending in this application. No amendments to the claims have been made in this response and therefore, Claims 41-51 remain pending for examination on the merits.

Restriction Requirement

The examiner has required restriction to one of the groups set forth in the Office Actions as follows:

- I. Claims 41-42, drawn to a composition of *N*-{2-[4-(3-phenyl-4-methoxyphenyl)aminophenyl]ethyl}-(*R*)-2-hydroxy-2-(8-hydroxy-2(1*H*)-quinolinon-5-yl)ethylamine.
- II. Claims 43-44, drawn to a multiple active ingredient composition containing *N*-{2-[4-(3-phenyl-4-methoxyphenyl)aminophenyl]ethyl}-(*R*)-2-hydroxy-2-(8-hydroxy-2(1*H*)-quinolinon-5-yl)ethylamine and a steroidal anti-inflammatory agent.
- III. Claim 45, drawn to a multiple active ingredient composition of *N*-{2-[4-(3-phenyl-4-methoxyphenyl)aminophenyl]ethyl}-(*R*)-2-hydroxy-2-(8-hydroxy-2(1*H*)-quinolinon-5-yl)ethylamine and another agent.
- IV. Claims 46-49, drawn to a method of treating a disease condition associated with β 2 adrenergic receptor activity.
- V. Claims 50-51, drawn to a method of treating a disease condition associated with β 2 adrenergic receptor activity with a composition of claim 41 together with an anti-inflammatory agent.

In addition, the examiner has indicated that for Groups III and V, election of a single species is required and further restriction will be imposed based on the election of a single species. For the following reasons, Applicants respectfully traverse this requirement for restriction.

First, the examiner has not made a proper showing that examination of Groups I, II, and III would impose a serious burden. The restriction of Groups I (Claims 41-42), II (Claims 43-44) and III (Claim 45) is improper because a search of all three groups can be made without serious burden. If a search and examination of an entire application can

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be made without serious burden, the Examiner must examine the application on the merits even though it includes claims to independent and distinct inventions. In the present case, Claims 41-45 all read on a composition comprising the active ingredient, *N*-{2-[4-(3-phenyl-4-methoxyphenyl)aminophenyl]ethyl}-(*R*)-2-hydroxy-2-(8-hydroxy-2(1*H*)-quinolinon-5-yl)ethylamine. Any search for a composition including the specific active ingredient will, of necessity, provide references to compositions in which the active ingredient is present along with another therapeutic agent. Accordingly, the present restriction requirement is improper and withdrawal of the restriction of Groups I, II, and III is respectfully requested.

Second, as recited above, in the case of Groups III and V, the examiner has indicated that further restriction will be imposed based on the election of a single species. In particular, in Group III, the examiner has required election of a single disclosed compound to be combined with the active ingredient and has stated that "further restriction based on the species election will be required." Such a restriction within a claim is improper according to the courts and the MPEP.

More specifically, in *In re Weber, Soder and Boksay*, the court stated:

As a general proposition, an applicant has a right to have *each* claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not affect the right of the applicant eventually to have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on the merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification. *In re Weber, Soder, and Boksay*, 580, F.2d 455, 458-459, 198 U.S.P.Q. 328, 331-332 (C.C.P.A. 1978) (emphasis in original).

Additionally, according to MPEP §803.02, "[s]ince the decisions in *In re Weber*...and *In re Haas*..., it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention." In the present Office Action the Examiner has not provided a showing of lack of unity of invention *within* the claims of Groups III and V. For this reason, as well, the present restriction requirement is improper.

With respect to the restriction of the method of treatment claims, Groups IV and V, Applicants respectfully submit that search for the product and method claims together would not impose an undue burden. In the present application, the method claims 46-51 include all of the limitations of the product claim. Any search for the specific product of Claim 41 will of necessity also reveal references in which the specific product is used for treatment of disease. The restriction of Groups IV and V may, however, be rendered moot. As quoted in the Office Action, "Where applicant elects claims directed to the product and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP §821.04."

In view of the foregoing, Applicants submit that the requirement for restriction/election put forth in the Office Actions is improper and respectfully request that the restriction requirement be reconsidered and withdrawn.

Election

Although traversing the restriction requirement for the above reasons, to comply with 37 C.F.R. §1.143, Applicants hereby elect Group I, Claims 41-42.

Amendment of Inventorship Pursuant to 37 C.F.R. §1.48(b)

Applicants submit herewith, by separate paper, a request to amend the inventorship of this application pursuant to 37 C.F.R. §1.48(b). Entry of this amendment is respectfully requested.

Conclusion

Reconsideration of this application in view of the above remarks and early examination on the merits is respectfully requested. In the event, the examiner does not withdraw the restriction requirement; Applicants respectfully request a telephone interview with the examiner. Should the examiner wish to schedule a discussion, the examiner is invited to telephone the undersigned agent for Applicants at (650) 808-3764 (direct).

Respectfully submitted,

THERAVANCE, INC.

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By: Roberta P. Saxon
Roberta P. Saxon, Ph.D.
Registration No. 43,087

THERAVANCE, INC.
901 Gateway Boulevard
South San Francisco, CA 94080
Tel: (650) 808-6000
Fax: (650) 808-6078

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